IRB PERFORMANCE REVIEW

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TYPE PRODUCT(S): (I), D, H, F, N. R, S

DATA ACCESSION NO(S). 241131

PRODUCT MGR. NO. 17

PRODUCT NAME(S) Natural Herbal Flea Collar

COMPANY NAME Natural Research People, Inc.

SUBMISSION PURPOSE Registration

CHEMICAL & FORMULATION oil of pennyroyal

oil of eucalyptus

oil of cedar

oil of citronella

oil of rue

200.0 Introduction

The submission is an application for registration of Natural Herbal Flea Collar for cats and dogs. The collar contains certain natural oils: pennyroyal, eucalyptus, cedar, citronella, and rue. The proposed claim is that the collar "aids in control of flea problems naturally." Directions specify to "replace when effectiveness diminishes or in 30 days."

201.0 Data Summary

The data consist of a kennel trial with individually caged dogs and a laboratory test.

In the kennel trial the test animals were selected to randomize body weight, sex, type coat, and pretesting flea population densities. A total of 14 test dogs and 6 untreated check dogs were included in the testing. The cat flea was used to infest the dogs at an infestation rate of 100 fleas per animal. Pre-treatment infestations were conducted to determine suitability of the test animals at 6 and 3 days pretesting (before the collars were placed on the test dogs). In addition to the initial infestation after the collars were placed on the animals, there were reinfestations at 15 and 29 days after the beginning of the test. Counting procedure recorded the total number of fleas on each dog at 1, 3 and 5 days after each infestation. Data included the total number of fleas at various anatomical locations on each dog.

In the laboratory test a 1-inch section of collar was incubated at 72 $\pm$ 2°F in a quart jar with 10 fleas. Sections of fresh collars and sections of collars which had been on dogs for 16 days were tested (3 replicates for each collar age).

Results for the kennel test indicated that for the initial infestation period percent control at 1, 3 and 5 days post infestation was 35.2, 40.7 and 64.4; respectively. At the second infestation period (day 14 after the beginning of the test) percent control at 1, 3 and 5 days post-infestation was 18.2, 18.1, and 7.6. At the third infestation period (day 28 after the beginning of the test) percent control at 1, 3 and 5 days post infestation was 9.28, 10.65, and 22.3. Refer to Figure 1 for a graph of percent control for the 33-day test period and to Figure 2 for a graph of mean number of fleas per dog for treated and untreated control animals for the 33-day test period. It should be noted that the data from one dog [7-660] was not included in the calculations because of abnormally high flea counts after each infestation. The degree of control is based on 13 dogs.

The percent fleas observed according to body location on the animals is shown in Table 1. Counts for the head and neck areas indicate a reduction in percent fleas counted on the treated dogs at the period after initial infestation as compared to the two pre-treatment counting periods. The mean number of fleas per dog for each infestation period is shown in Table 2.

The results of the laboratory test of the collar sections indicate that for fresh collars the mean number of dead fleas at 4, 8, and 24 hours was 9.67, 10 and 10 respectively. There were no dead fleas in the controls. For the 16-day old collars, the mean number of dead fleas was 10 for all 3 counting periods. There were no dead fleas in the controls.

202.0 Conclusions

There was a 64.4 percent level of flea control at 5 days after the initial infestation (when the collars had been placed on the dogs at the start of the test) with diminished activity through 33 days. There is no way to determine if activity increased between 5 and 15 days since there were no counts during this interval. The data indicate that differences in coat length and animal weight of collared dogs were not reflected in differences in flea counts. The data showing percent fleas observed according to location on animals do not conclusively demonstrate repellent activity of the collar.

The data do not support the proposed claim for aids in control of flea problems on dogs.

The proposed claim for use on cats is not acceptable. This claim should be supported with test data for cats.

The data indicate that the collar may reduce fleas on dogs by up to 64% for a period of 5 days after the collar is placed on the dog. However, this is not conclusively demonstrated with a test which included only 13 dogs. Additional data would be necessary to show activity of the collar. On March 3, 1980 at 9:00 A.M., a meeting was held with D. B. Tyler who represents the applicant. IRB-TSS personnel at this meeting included Dr. A. Tarsey, P. O. Hutton and R. S. Van Denburgh, as well as a representative of PM Team 17. The data were discussed with Mr. Tyler at that time. It was indicated by IRB-TSS that additional testing was needed. It was also indicated that the record showed that in 1978 the applicant had indicated that the collar was to be tested by veterinarians in a program in which dog owners would report on performance for a 30-day period. Mr. Tyler indicated that this testing had not been done. It was indicated by IRB-TSS that possibly a claim that the collar "may reduce fleas on dogs for a

5-day period" could be accepted on the basis of conditional registration which would require that there was additional testing, including the field testing by veterinarians which was to have been initiated in 1978.

IRB-TSS would not recommend full registration of a flea collar claim based on data from only 13 dogs since this would not be enough animals to conclusively demonstrate performance.

R. S. Van Denburgh
3-7-80

EPA Registration No. 42443-1

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Pages 5 through 6 are not included in this copy.

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___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

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